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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,528	SCHNORR ET AL.	
	Examiner	Art Unit	
	CATHERINE S. HIBBERT	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-47* is/are pending in the application.

4a) Of the above claim(s) *40-42 and 45-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-39,43 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the First Action on the Merits of US 10/576,528, filed 19 April 2006, which is a National Phase entry of PCT/DK2004/000734, filed 26 October 2004, which claims benefit of US Provisional 60/515,927, filed 30 October 2003, and claims Foreign Priority to Denmark Patent Application 2003 01607, filed 30 October 2003. Claims 1-28 are cancelled. Claims 29-47 are new. Claims 29-47 are pending. Claims 40-42 and 45-47 are withdrawn to non-elected subject matter. Claims 29-39 and 43-44 are under examination in this action.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-2, 15-17 and 19-20) and of the species “cellulases” as the species of enzyme recited in Claim 17, in the reply filed on 9 September 2008 is acknowledged. Applicants submit that Claims 29-47 read on the elected species. The traversal is on the ground(s) that Applicants argue that the inventions designated I-IV are related as product, process for the manufacture of the product, and use of the product. Furthermore, Applicants submit that these “classes of inventions comply with the unity of invention standard”. Applicants point out that “no objection to unity of invention was raised at any point of the PCT prosecution”.

This is respectfully not found persuasive because the decision to break or maintain unity of invention during the PCT prosecution does not affect the decision to break unity of invention for the prosecution of the instant case. In addition, the inventions listed as Groups I-IV lack the same or corresponding "special technical feature" because the common technical feature that unifies the invention groups is not

considered a "special technical feature" because the technical feature of the claims does not make a contribution over the prior art. The PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. The technical feature of the claims is a carbohydrate-binding module. However, the claimed carbohydrate-binding module is broadly claimed as "an amino acid sequence" of SEQ ID NO:2. For example, Claim 1 is drawn to a carbohydrate-binding module which is a polypeptide homologous to SEQ ID NO:2, which polypeptide has an amino acid sequence of at least 50% identity with positions 34-174 of SEQ ID NO:2 (see instant claim 1, part c). The phrase "an amino acid sequence" reads broadly on any dipeptide of the sequence having 50% identity to the sequence 34-174 of SEQ ID NO:2. Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims. The carbohydrate-binding domain, as broadly claimed, does not represent an advance over the art (see Levy et al, "Cellulose-binding domains--Biotechnological applications", cited in search report) and hence there is no unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claims 40-42 and 45-47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 40-42 and 45-47 are *methods* of using the carbohydrate-binding module of Claims 29 and 43, respectively but the elected invention is drawn to a carbohydrate-binding module *product.* The product and process claims are properly considered

distinct inventions because it has been determined that the inventions lack unity of invention. The inventions listed as Groups I-IV lack the same or corresponding "special technical feature" because the common technical feature that unifies the invention groups is not considered a "special technical feature" because the technical feature of the instant claims, as written, does not make a contribution over the prior art (see just above).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40-42 and 45-47 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The use of the trademark Avicel has been noted in this application (e.g. p. 2, line 22). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 34 is objected to because of the following informalities: The claim is missing a period at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite because it is unclear whether the phrase “which has carbohydrate-binding module activity” in line 2 is meant to limit the term "fragment" in line 1 or rather pertains to the term “the sequence of amino acids 34-174 of SEQ ID NO:2” which just precedes the phrase “which has carbohydrate-binding module activity”. Therefore, one of ordinary skill in the art would not be able to determine the metes and bounds of Applicants invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-39 and 43-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not a sufficient characteristic for written description purposes, even

when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include: (1) Actual reduction to practice, (2) Disclosure of drawings or structural chemical formulas, (3) Sufficient relevant identifying characteristics (such as: i. Complete structure, ii. Partial structure, iii. Physical and/or chemical properties, iv. Functional characteristics when coupled with a known or disclosed, and correlation between function and structure), (4) Method of making the claimed invention, (5) Level of skill and knowledge in the art, and (6) Predictability in the art.

"Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient."

MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to a genus of isolated carbohydrate-binding modules having carbohydrate-binding module activity, the modules selected from the group consisting of: (a) a polypeptide encoded by a DNA sequence which has at least 80% identity with the sequence of nucleotides 109-531 of SEQ ID NO: 1; (b) a polypeptide having a sequence which has at least 80% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2; (c) a polypeptide encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ I D NO: 1 under high stringency conditions; and (d) a polypeptide which is a fragment of the sequence of amino acids 34-174 of SEQ ID NO: 2.

Initially it is noted that claims must be given their broadest reasonable interpretation in light of the instant specification during examination. Therefore, it is noted that the base Claim 29 reads on an isolated carbohydrate-binding module which is "**a polypeptide**" comprising "**a sequence"** which has at least 80% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2. It is noted that an amino acid sequence that is the dipeptide glycine-glycine, or serine-serine, or alanine-valine, for example, would each read on **a sequence** which has at least 100% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 29-39 and 43-44 are broad and generic, with respect to all

possible compounds encompassed by the claims. The possible structural variations are numerous to any polypeptide which is a fragment of the sequence of amino acids 34-174 of SEQ ID NO:2. In addition, the dependent Claims 34-39 and 43-44 do not remedy the written description requirement because they also claim the carbohydrate-binding module of Claim 29. Furthermore, Claims 30-33 are not remedial as they specify that the carbohydrate-binding module of claim 29 comprise **a sequence** which has at least 80%, 85%, 90% and 95% identity, respectively, with the sequence of amino acids 34-174 of SEQ ID: NO:2.

Specifically, the claims lack written description because although one of ordinary skill in the art could reasonably predict the amino acid sequence (structure) of a given polypeptide that was a fragment of SEQ ID NO: 2 or that had a given % identity to the known SEQ ID NO: 2 and also could reasonably predict a polypeptide structure encoded by a DNA sequence having at least 80% identity with the nucleotide sequence 109-531 of SEQ ID NO: 1, it is clear that experimentation would be required to determine whether any of these given polypeptide sequences, having 95% (or less) identity with the sequence of amino acids 34-174 of SEQ ID NO: 2 , would meet the functional requirement “wherein the polypeptide has carbohydrate-binding module activity”. For example, the instant specification recites on page 2, lines 20-23: "It is contemplated that new CBD's can be found by cloning cellulase, xylanases or other plant cell wall degrading enzymes and measure the binding to e.g. cellulose. If the enzyme activity is bound to Avicel under the standard conditions described below, it can be assumed that part of the gene codes for a binding domain”. Therefore, one of

ordinary skill in the art would not be able to determine which of the species of carbohydrate-binding module sequences would have carbohydrate-binding module activity without experimentation and thus the structure-function correlation is considered to be unpredictable. In addition, regarding Claim 29, the limitation of part (c) directed to "a polypeptide encoded by a DNA sequence that hybridizes to the DNA sequence of nucleotides 109-531 of SEQ ID NO:1 under high stringency conditions" lacks written description because the *structure* requirement for this limitation as well as the functional requirement is unpredictable.

Although the claims recite some functional characteristics, the claims lack written description because there is no disclosure of a *correlation* between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description of SEQ ID NO: 1, the nucleotide sequence 109-531 of SEQ ID NO:1, and SEQ ID NO: 2 and the amino acid sequence 34-174 of SEQ ID NO: 2, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims. For example, the specification does not provide a representative number of examples of sequences that have at least 95% identity with or are fragments of the sequence of amino acids 34-174 of SEQ ID NO: 2 such that one of ordinary skill in the art would be able to envision the next species of the genus of polypeptides that have carbohydrate-binding module activity.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession *of the entire scope* of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-38 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourne and Henrissat in "Glycoside hydrolases and glycosyltransferases: families and functional modules" (Current Opinion in Structural Biology, 2001, Vol. 11;pp 593-600, made of record in the IDS).

Initially it is noted that claims must be given their broadest reasonable interpretation in light of the instant specification during examination. Therefore, it is noted that the base Claim 29 reads on an isolated carbohydrate-binding module which

is "**a polypeptide**" comprising "**a sequence"** which has at least 80% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2. It is noted that an amino acid sequence that is the dipeptide glycine-glycine, or serine-serine, or alanine-valine, for example, would each read on **a sequence** which has at least 100% identity with the sequence of amino acids 34-174 of SEQ ID NO: 2.

Bourne and Henrissat teach many different carbohydrate-binding modules that are polypeptides comprising the dipeptide glycine-glycine, serine-serine, or alanine-valine and that are contained in (e.g. are in a composition with) cellulases and endoglucanases (e.g. page 593, Table 1 and page 597, Table 3). Bourne and Henrissat specifically teach isolated carbohydrate-binding modules (e.g. page 597, paragraph 3). In addition, one of ordinary skill in the art could reasonably interpret the carbohydrate-binding module contained in an isolated enzyme to read on an isolated carbohydrate-binding modules, especially in light of the description of a CBM in the instant specification (page 1, paragraph 2).

In addition, regarding Claim 36, the MPEP states that Product-By-Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps" and further states that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production" (MPEP 2113 [R-1]). Therefore, absent evidence to the contrary, the limitation of "a DNA sequence obtained from" *P. nigrella* CBS 444.97, in Claim 36, is not further limiting to the base claim 29.

Therefore, Bourne and Henrissat anticipate all the limitations of Claims 29-38 and 43.

Claims 29-39 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Levy and Shoseyov in "Cellulose-binding domains Biotechnological applications" (Biotechnology Advances, 2002, Vol. 20;pp 191-213, made of record in the IDS).

Claims are as described above. Claims 39 and 44 are directed to detergent compositions comprising the CMB of claims 29 and 43, respectively, and a surfactant.

Levy and Shoseyov teach carbohydrate-binding modules that are polypeptides that inherently comprise the dipeptides glycine-glycine, serine-serine, and/or alanine-valine. For example, Levy and Shoseyov teach cellulases and endo-beta-1,4-glucanases that contain CBDs and contemplate hybrid enzymes or fusion proteins (e.g. page 192 and 194, Figure 1 and legend). Levy and Shoseyov teach combining CBD's in detergent compositions (e.g. page 197, paragraph 1, lines 1-4).

Therefore, Levy and Shoseyov anticipate all the limitations of Claims 29-39 and 43-44.

State of the Art

An isolated carbohydrate-binding module consisting of a polypeptide consisting of amino acids 34-174 of SEQ ID NO: 2 and an isolated carbohydrate-binding module consisting of a polypeptide encoded by a DNA sequence consisting of nucleotides 109-531 of SEQ ID NO: 1 are free of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE S. HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Catherine S. Hibbert/Examiner/AU1636